

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH DAKOTA
WESTERN DIVISION

TERRI BRUCE,

Case No. 17-5080

Plaintiff,

vs.

STATE OF SOUTH DAKOTA and
LAURIE GILL, in her official capacity as
Commissioner of the South Dakota Bureau
of Human Resources,

Defendants.

EXPERT DECLARATION of Paul W Hruz, M.D., Ph.D

1. I have been retained by counsel for Defendants as an expert in connection with the above-captioned litigation. I have actual knowledge of the matters stated in this declaration. My professional background, experience, and publications are detailed in my curriculum vitae, a true and accurate copy which is attached as Exhibit A to this declaration.

2. I received my doctor of philosophy degree from the Medical College of Wisconsin in 1993. I received my medical degree from the Medical College of Wisconsin in 1994. I am an Associate Professor of Pediatrics in the Division of Pediatric Endocrinology and Diabetes at Washington University School of Medicine. I also have a secondary appointment as Associate Professor of Cellular Biology and Physiology in the Division of Biology and Biological Sciences at Washington University School of Medicine. I served as chief of the Division of Pediatric

Endocrinology and Diabetes at Washington University from 2012-2017. I served as the Director of the Pediatric Endocrinology Fellowship Program at Washington University from 2008-2016.

3. I am board certified in Pediatrics and Pediatric Endocrinology. I have been licensed to practice medicine in Missouri since 2000.

4. My professional memberships include the American Academy of Pediatrics, the Pediatric Endocrine Society, and the Endocrine Society.

5. I have extensive experience in treating infants and children with disorders of sexual development and am an active member of the multidisciplinary Disorders of Sexual Development (DSD) program at Washington University. The DSD Team at Washington University is part of the DSD-Translational Research Network, a national multi-institutional research network that investigates the genetic causes and the psychologic consequences of DSD.

6. In the nearly 20 years that I have been in clinical practice I have participated in the care of hundreds of children with disorders of sexual development. In the care of these patients, I have acquired expertise in the understanding and management of associated difficulties in gender identification.

7. In my role as the director of the Division of Pediatric Endocrinology at Washington University, I have extensively studied the existing literature related to the incidence, potential etiology and treatment of gender dysphoria as efforts were made to develop a Transgender clinic at Saint Louis Children's Hospital. I have participated in local and national meetings where the endocrine care of gender dysphoria has been discussed and debated. I have met individually with several pediatric endocrinologists, including Dr. Norman Spack, who have developed and led transgender programs in the United States. I have also met with adult patients and parents of

children with gender dysphoria to understand the unique difficulties experienced by this patient population.

8. Patients referred to our practice for the evaluation and treatment of gender dysphoria are cared for by an interdisciplinary team of providers that includes a psychologist and pediatric endocrinologist who have been specifically chosen for this role based upon a special interest in this rare patient population. Due to serious concerns regarding the safety, efficacy, and ethics of the current treatment paradigm, I have not directly engaged in hormonal treatment of patients with gender dysphoria.

9. My opinions as detailed in this declaration are based upon my knowledge and direct professional experience in the subject matters discussed. The materials that I have relied upon are the same types of materials that other experts in my field of clinical practice rely upon when forming opinions on the subject. The documents that I have reviewed specifically related to this case are 1.) The Plaintiff complaint for Terri Bruce 2.) The Defendants' Answer to Plaintiff's Complaint. 3.) The Defendants' answers to Plaintiff's First Set of Interrogatories, 4.) The expert witness declaration and supplemental report of Dr. George Brown, 5.) The expert witness declaration of Dr. Anne Dilenschneider. 6.) Medical Records from Dr. Synder, 7.) The September 1, 2017 medical note by Dr. Buehner, 8.) Medical Dr. Luther's denial of a pre-authorization for a mastectomy, and 9.) The State of South Dakota Health Plan. A list of the published literature I have relied on is attached as Exhibit B to this declaration.

10. Over my career, I have provided expert medical record review and testified at deposition in less than a dozen cases. Related to the litigation of issues of sex and gender, I have been designated as an expert witness in *Joaquín Carcaño et al vs. Patrick Mccrory* (US District Court, Middle District of North Carolina, Case No. 1:16-CV-00236-TDS-JEP), *Jane Doe vs Board of*

Education of the Highland School District (Ohio District Court, Eastern Division, Case No. 2:16-cv-524), *Ashton Whitaker vs. Kenosha Unified School District* (US District Court, Eastern District of Wisconsin, Case No. 2:16-cv-00943), and *Drew Adams vs. Florida School District* (US District Court for the Middle District of Florida, Jacksonville Division, Case No. 3:17-cv-00739- TJCJBT). I have been deposed in the last two of these cases. In the past 4 years I have also served as an expert witness in *Dakota Humphrey vs. Stanley Block and Liston Ward et al. vs. Janssen Pharmaceuticals* (Missouri Circuit Court, Case No. 1422-CC08940). I have never testified at trial.

11. I am being compensated at an hourly rate for actual time devoted, at the rate of \$350 per hour. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I provide.

Basic Terminology

12. Biological sex is a term that specifically refers to a member of a species in relation to the member's capacity to either donate (male) or receive (female) genetic material for the purpose of reproduction. This remains the standard definition that has been accepted and used by scientists, medical personnel, and society in general.

13. Gender, a term that had traditionally been reserved for grammatical purposes, is currently used to describe the psychologic and cultural characteristics of a person in relation to biological sex. Gender therefore exists in reference to societal perceptions, not biology.

14. Gender identity refers to a person's individual perception of being male or female.

15. Sexual orientation refers to a person's arousal and desire for sexual intimacy with members of the male or female sex.

Human sexuality in relation to fundamental biology and observed variations

16. Sex is genetically encoded at the moment of conception due to the presence of specific DNA sequences (i.e. genes) that direct the production of signals that influence the formation of bipotential gonad to develop into either a testis or ovary. This genetic information is normally present on X and Y chromosomes. Chromosomal sex refers to the normal complement of X and Y chromosomes (i.e. human males have one X and one Y chromosome whereas human females have two X chromosomes). Genetic signals are mediated through the activation or deactivation of genes and through programmed signaling of hormones and cellular transcription factors. Specific information directing male sexual development is contained within the sex-determining region of the Y chromosome (SRY). Without SRY, female sexual development occurs.
17. For members of the human species, sex is normatively aligned in a binary fashion (i.e. either male or female) in relation to biologic purpose. Medical recognition of an individual as male or female is typically made at birth according to external phenotypic expression of primary sexual traits (i.e., presence of a penis for males and presence of labia and vagina for females).
18. Due to genetic and hormonal variation in the developing fetus, normative development of the external genitalia in any individual differs with respect to size and appearance while maintaining an ability to function with respect to biologic purpose (i.e. reproduction). Internal structures (e.g. gonad, uterus, fallopian tubes, vas deferens) normatively align with external genitalia.
19. Reliance upon external phenotypic expression of primary sexual traits is a highly accurate

means to assign biologic sex. In over 99.9% of cases, this designation will correlate with internal sexual traits and capacity for normal biologic sexual function. Sex is therefore not “assigned at birth” but is rather recognized at birth.

20. In addition to directing the prenatal development of primary sexual organs, genetic and epigenetic programming present in every cell in the body influences numerous postnatal developmental changes. The biological function of the ovary in females and testes in males is largely controlled by highly orchestrated neuronal and hormonal signaling in the brain at the level of the hypothalamus and pituitary gland. The hypothalamic, pituitary, gonadal (HPG) axis is normally active at the time of birth but is actively suppressed during most of childhood development. Puberty (i.e. sexual maturation that leads to reproductive capacity) is initiated when the HPG axis is reactivated. Maturation of the gonads leads to testicular sperm production in males and ovarian follicle development in females. This is accompanied by increase of sex-steroid hormones. Testosterone and estrogen are the predominant hormones in males and females, respectively. Development of secondary sexual characteristics (i.e. physical features that are not directly involved in reproduction) include increased lean body mass, facial hair, and deepening of the voice in males and increased adiposity, hip widening, and breast development in females. Most males will experience puberty between 9 and 14 years of life. Most females will experience puberty between 8 and 13 years.

20. Due to the complexity of signals that are involved in normal sexual development, it is not surprising that a small number of individuals are born with defects in this process. Defects can occur either through inherited or *de novo* mutations in genes that are involved in sexual determination or through environmental insults during critical states of sexual development.

Persons who are born with such abnormalities are considered to have a disorder of sexual development (DSD). Most often, this is first detected as ambiguity in the appearance of the external genitalia. Normal variation in external genital appearance (e.g. phallic size) does not alter the basic biologic nature of sex as a binary trait. “Intersex” conditions represent disorders of normal development, not a third sex.

Gender Dysphoria in relation to Biological Sex

21. Although gender usually aligns with biological sex, some individuals experience discordance in these distinct traits. Specifically, biologic females may identify as males and biologic males may identify as females. As gender by definition is distinct from biological sex, one’s gender identity does not change a person’s biological sex.

22. Individuals who experience significant distress due to discordance between gender identity and sex are considered to have “gender dysphoria”.¹ Although the prevalence of gender dysphoria has not been established by rigorous scientific analysis, estimates reported in the DSM-V are between 0.005% to 0.014% for adult males and 0.002% to 0.003% for adult females.¹ Thus, gender dysphoria is a rare condition. Recent data indicates that the number of people seeking care for gender dysphoria is increasing with some estimates as high as 20-fold.^{2,3} Self-reported prevalence rates currently range from 0.5 to 1.3% of all children, adolescents and adults.⁴ It is frequently hypothesized that the earlier low prevalence estimates are contributed by under-reporting of this condition and that more patients with this condition are now coming forward for treatment. An alternate hypothesis is that changing societal acceptance of transgenderism and the growing number of medical centers providing medical intervention for gender dysphoria is affecting the number of persons who identify as transgender.

23. Terri Bruce, like most people with gender dysphoria, does not have a disorder of sexual development. As reflected in the complaint and available medical records, Terri Bruce was born with normally formed and functioning female sexual organs. The presence of a uterus and functional ovaries prior to the initiation of testosterone administration is evidenced by spontaneous breast development and menses.

24. There is strong evidence against the theory that gender identity is determined at or before birth and is unchangeable. This comes from identical twin studies where siblings share genetic complements and prenatal environmental exposure but have differing gender identities.⁵ Further evidence that gender identity is not fixed comes from established peer reviewed literature demonstrating that the vast majority (80-95%) of children who express gender dysphoria revert to a gender identity concordant with their biological sex by late adolescence.^{6,7} It is not known whether individuals with gender dysphoria persistence have differing etiologies or severity of precipitating factors compared to desisting individuals. It is also not possible to determine *a priori* which children will experience resolution of their gender dysphoria without treatment and which children will continue to have gender dysphoria after reaching adulthood. This uncertainty has important implications in making recommendations for medical interventions in affected patients. In particular, for children who would otherwise experience spontaneous realignment of gender identity with biological sex, medical interventions to alter sexual appearance are unnecessary and expose patients to potentially irreversible adverse effects.

25. The etiology of gender dysphoria in individuals with sex/gender discordance remains to be identified. Theories include prenatal hormone exposure, genetic variation, and postnatal environmental influences. Based upon the currently available but incomplete dataset, it is likely

that gender dysphoria is multifactorial with differing qualitative and quantitative influences in any given individual.⁸

26. The recently coined concept of “neurological sex” as a distinct entity or a basis for classifying individuals as male or female has no scientific justification. Limited emerging data has suggested structural and functional differences between brains from normal and transgender individuals. These data do not establish whether these differences are innate and fixed or acquired and malleable. The remarkable neuronal plasticity of the brain is known and has been studied extensively in gender-independent contexts related to health and disease, learning and behavior. Thus, an alternate hypothesis to the theory that structural differences in the brain are the cause of gender dysphoria is that these differences are due to adaptive changes in response to cultural and behavioral influences.⁹

Gender Ideology

27. The modern attempt to equate gender identity with sex is not based upon sound scientific principles but rather is based upon ideology fueled by advocacy. Although worldviews among scientists and physicians, similar to society at large, differ, science is firmly grounded in physical reality not perception. The inherent link between human sexual biology and teleology is self-evident and fixed.

28. The claims of proponents of transgenderism, which include opinions such as “Gender identity is the primary factor determining a person’s sex” and “Gender is the only true determinant of sex” must be viewed in their proper philosophical context. There is no scientific basis for redefining sex on the basis of a person’s psychological sense of ‘gender’.

29. The prevailing, constant and accurate designation of sex as a biological trait grounded in the inherent purpose of male and female anatomy and as manifested in the appearance of external genitalia at birth remains the proper scientific and medical standard. Redefinition of the classification and meaning of sex based upon pathologic variation is not established medical fact.

Potential Harm Related to Gender Dysphoria Treatments

30. The fundamental purpose of the practice of medicine is to treat disease and alleviate suffering. An essential tenet of medical practice is to avoid doing harm in the process. Due to frequent lack of clear and definitive evidence on how to best accomplish this goal, treatment approaches can and do frequently differ among highly knowledgeable, competent, and caring physicians.

31. Persons with gender dysphoria as delineated in the DSM-V experience significant psychological distress related to their condition with elevated risk of depression, suicide, and other morbidities. Thus, attempts to provide effective medical care to affected persons are clearly warranted. Several approaches have been proposed to alleviate gender dysphoria in affected individuals. These approaches are not limited to surgical procedures. Recognizing the frequent presence of co-morbidities in affected patients, psychological counseling, both for patients and affected family members, to address any associated depression, anxiety, substance abuse, autism, schizophrenia or eating disorders has long been endorsed. Current interventions also include social affirmation, GnRH agonists to suppress pubertal development in affected children, and cross-sex hormone administration as patients enter into adulthood. Surgical approaches to alter the appearance of the breast (often referred to as “top surgery”) include mastectomy for females desiring to appear as males and breast augmentation for males desiring to appear as females.

Surgical approaches to alter the appearance of the external genitalia (often referred to as “bottom surgery”) include penile inversion vaginoplasty for males desiring to appear as females and phalloplasty for females desiring to appear as males. These medical tools are all aimed at aligning the physical appearance of the body with an individual’s gender identity and suppressing any discordant sex phenotype.

32. Most physicians agree that efforts to effectively treat persons with gender dysphoria require respect for the inherent dignity of those affected, sensitivity to their suffering, and maintenance of objectivity in efforts to assess etiologies and long-term outcomes. The claim that surgical mastectomy is medically necessary as a means to alleviate gender dysphoria and prevent suicide is not supported by the currently available scientific and medical evidence. Limitations of the existing medical literature prevent definitive conclusions regarding long-term safety and efficacy.^{10,11}

33. Research on outcomes of cross-sex hormone administration and gender confirming surgery is widely acknowledged to be low quality with a high risk of study bias.^{12,13} Among the most frequently cited deficiencies of the published literature are small samples sizes, a preponderance of observational studies, general lack of prospective randomized controlled trials, absence or poor selection of control subjects, and frequent reliance on convenience samples. Efforts to understand long-term safety and efficacy are also hindered by high rates of patients being lost to follow-up.

34. The gender affirming approach, which includes cross-sex hormone administration with or without surgery to align external appearance to align with gender identity rather than biological sex has limited scientific support for short-term alleviation of dysphoria and no long-term outcomes data demonstrating superiority over the other approaches. Claims that the other

approaches have been scientifically disproven are false. Decades of research, most notably the pioneering work of Dr. Kenneth Zucker, have supported the efficacy of a more conservative approach for the majority of patients experiencing gender dysphoria.^{14,15} For children who would otherwise experience spontaneous realignment of gender identity with biological sex, use of hormonal therapy including puberty blockade exposes these patients to unnecessary and potentially irreversible harm.

35. Long-term follow up of patients with gender dysphoria who have undergone social and hormonal transition with or without surgical intervention reveals persistent psychological morbidity far above non-transgendered individuals with suicide attempts 7-fold and completed suicides 19-fold above the general population.^{16,17} Although the Dhejne study was not designed to answer the question of whether surgery influenced suicide rates, it clearly indicates that this intervention did not solve the problem. It is important to note that all-cause mortality rates were elevated in subjects who had undergone medical transition, but this difference was not observed until more than 10 years of follow-up. A meta-analysis of 42 studies recently reported that reported suicide rates in transgendered individuals were similar when measured across the lifetime and within the past year.¹⁶ In the limited number of studies that reported suicide rates before and after transition, rates were found to be higher after medical intervention. While acknowledging the need for appropriate caution in extrapolating the outcomes observed from prior studies with current treatments, the available evidence showing persistently elevated rates of depression, anxiety, substance abuse and suicide far above the background population in adults who have undergone medical transition alone justifies extreme caution in widespread adoption of this practice.

36. In standard medical practice, a measured approach is used generally when dealing with complex medical issues where there is insufficient or conflicting scientific evidence regarding the risk or benefit of a proposed treatment. This includes careful weighing of potential risks and benefits. Recognition of poor quality of scientific evidence for benefit of hormonal and surgical interventions designed to treat gender dysphoria was a primary basis for the 2016 National Coverage Decision (NCD) by the U.S. Department of Health and Human Services (HHS). In this decision, it was concluded that there was insufficient evidence to establish universal coverage. As contained in Dr. Brown's supplemental report (Exhibit C), the 2016 HHS memo specifically noted "gaps in the evidentiary base" and a remaining need for "robust clinical studies" to establish safety and effectiveness of transgender surgery. Acknowledgement of significant knowledge gaps and need for additional research is not limited to HHS. Hayes, Inc., an independent research and consulting firm that evaluates the safety of medical technologies, reported in 2014 the conclusion that the use of cross-sex hormones and "sex reassignment surgery" is based upon very low quality evidence.¹⁸ Similar statements reflecting the inadequacy of current scientific evidence have been made by nearly all professional organizations that have addressed the question of transgender treatment, including many of whom have endorsed the current paradigm of medical intervention.¹⁹

37. The Endocrine Society published in 2009 clinical guidelines for the treatment of patients with persistent gender dysphoria.²⁰ The recommendations include temporary suppression of pubertal development of children with GnRH agonists (hormone blockers normally used for children experiencing precocious puberty) followed by hormonal treatments to induce the development of secondary sexual traits consistent with one's gender identity. This guideline was developed using the GRADE (Recommendations, Assessment, Development, and

Evaluation) system for rating clinical guidelines. As directly stated in the Endocrine Society publication, “the strength of recommendations and the quality of evidence was low or very low.” According to the GRADE system, low recommendations indicate “Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate”. Very low recommendations mean that “any estimate of effect is very uncertain”. An updated set of guidelines was published in September of 2017.²¹ The low quality of evidence presented in this document persist. Thus, there remains significant uncertainty over the long-term benefit of medical interventions designed to alter the appearance of the human body to align with an individual’s gender identity when this is discordant with biological sex.

38. Clinical Practice Guidelines published by the World Professional Association for Transgender Health (WPATH), which is currently in its 7th iteration, similarly, though less explicitly, acknowledge the limitation of existing scientific data supporting their recommendations given and “the value of harm-reduction approaches”.²²

39. It is frequently asserted that administering GnRH agonists to suppress pubertal development in adolescent children with gender dysphoria is safe and fully reversible intervention, allowing children more time to explore their gender identity and alleviate negative feelings due to the physical changes induced by rising sex steroid levels. GnRH agonist act by disrupting normal pulsatile secretion of pituitary LH and FSH, thereby preventing the gonadal maturation that is caused by these hormones. Although cessation of puberty blockers is generally followed by reactivation of the HPG axis, disruption of the temporal relationship between the developmental processes of puberty and adolescence cannot be reversed. It can also be hypothesized that pubertal blockade influences desistence rates in children with sex/gender identity discordance. Safety claims are based upon evidence for the treatment of precocious puberty, an entirely

different medical condition. Prescription of GnRH agonists for the treatment of gender dysphoria represents “off-label use” of these drugs. GnRH agonists have not been adequately studied for the treatment of gender dysphoria and have therefore not been approved by the Food and Drug administration for this indication.

40. Treatment of gender dysphoric individuals with hormones (pubertal suppression and cross-hormone therapy) carries significant risk. It is generally accepted, even by advocates of transgender hormone therapy, that hormonal treatment results in sterility which in many cases, particularly when gonadal maturation is prevented by pubertal blockade, is irreversible.²³ In children and adolescents, emerging data also show that treated patients have lower bone density which may lead to increased fracture risk later in life.²⁴ Other potential adverse effects include disfiguring acne, high blood pressure, weight gain, abnormal glucose tolerance, breast cancer, liver disease, thrombosis, and cardiovascular disease.^{11,25} While some of the earlier reported risks may have been due to the doses and route of administration of hormone administration, more recent reports continue to show significant metabolic effects that are known to confer increased risk of cardiovascular disease.²⁶ The length of follow-up is insufficient to establish long-term safety.

41. Since strategies for the treatment of transgendered individuals as summarized by the Endocrine Society guidelines are relatively new, long-term outcomes are unknown. Evidence presented as support for short term reductions in psychological distress following social transition in a “gender affirming” environment remains inconclusive. When considered apart from advocacy based agendas, multiple potential confounders are evident. The most notable deficiencies of existing research are the absence of proper control subjects and lack of randomization in study design.

42. Contrary to Dr. Brown's assertion that there is no legitimate basis for the gender transformations exclusion in the South Dakota health plan (Declaration ¶36), this policy is justified by the lack of evidence for long-term efficacy of hormonal and surgical interventions in preventing suicide and other morbidity in patients with gender dysphoria. There are also legitimate concerns over the long-term safety of this approach. There remains a significant and unmet need to better understand the biological, psychological, and environmental basis for the manifestation of discordance of gender identity and biological sex in affected individuals.^{10,27} In particular, there is a concerning lack of randomized controlled trials comparing outcomes of hormone and surgical intervention with other treatment modalities including psychological support. This includes studies specifically addressing the long-term benefit of bilateral mastectomy for biological females desiring to appear as male over other potential treatment modalities. Such studies can be ethically designed and executed with provision of other dignity affirming measures to both treatment groups. Without this scientific evidence, it is not possible to make the assertion that surgery is an essential component of treatment.

43. Limitations on this report: My opinions and hypotheses in this matter are subject to the limitations of all documentary and related evidence, the impossibility of absolute prediction, as well as the limitations of social and medical science. I have not met with, nor interviewed, plaintiff Terri Bruce. As always, I have no expert opinions regarding the veracity of witnesses in this case. I have not yet reviewed all of the evidence in this case and my opinions are subject to change at any time as new information becomes available to me. Only the trier of fact can determine the credibility of witnesses and how scientific research may or may not be related to the specific facts of any particular case. A key role of an expert witness is to help the court, lawyers, parties, and the public understand and apply reliable scientific, technical, and

investigative principles, hypotheses, methods, and information. I have transmitted this confidential expert report directly to attorney Jerry Johnson, for distribution as consistent with the relevant laws.

Pursuant to 28 U.S.C § 1746, I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Date: May 21, 2018

Signed: Paul W. Hruz

Paul W. Hruz, M.D., Ph.D.